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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	4428.2US	6427

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EXAMINER
CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/081,953

**Applicant(s)**

HENNEN ET AL.

**Examiner**

Stacy B Chen

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☒ Claim(s) 1-19 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/9/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicant's amendment filed September 9, 2004 is acknowledged and entered. Claims 1-22 are pending and under examination.

#### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on September 9, 2004 was filed after the mailing date of the non-final Office action on May 6, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Response to Amendment***

3. The rejection of claims 1-22 under 35 U.S.C. 112, second paragraph, for being infinite for reciting unclear method steps relating to the treatment of an animal, is withdrawn in view of Applicant's amendment. The rejection of claim 22 for being indefinite for reciting, "strengthen an immune system", is withdrawn in view of Applicant's amendment.

#### ***Claim Objections***

4. Claims 1-19 and 22 are objected to for the following informality: Claim 1 and depending claims 2-19 and 22 contain a grammatical error in the phrase, "in a concentration greater than the present in the egg". The phrase should read, "in a concentration greater than that present in the egg". Correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 1 and depending claims 2-19 and 22 were amended to recite a new limitation that is not supported in the specification as originally filed. The new limitation is directed to the amount of transfer factor in the composition to be administered to an animal. The limitation recites that the transfer factor is “in a concentration greater than the [that] present in the egg”. There is no support in the specification for this limitation and Applicant has not pointed to any place in the specification for which there is support. The new limitation should be removed from the claim language unless Applicant points to support in the specification.

***Claim Rejections - 35 USC § 112***

6. Claim 11 and dependent claim 12 remain rejected under 35 U.S.C. 112, second paragraph for being indefinite for reciting “treat a disease state associated with infection by a pathogen associated with said antigenic agent”. Applicant argues that those of ordinary skill in the art understand a “disease state” to include various conditions that precede and accompany a disease,

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as well as the disease itself. Applicant provides an example, *H. pylori*, and the conditions that accompany and may result from an infection with *H. pylori*. In response, the Office acknowledges the breadth of the term, yet the term itself remains indefinite. The conditions that precede a disease are not defined. What are the conditions that precede a disease? For example, prior to a patient's diagnosis with an *H. pylori* infection, what preceding conditions are going to be treated with transfer factor? How would one know to administer transfer factor to a patient that does not even have the *H. pylori* infection? Further, the claims are drawn to conditions that are associated with infection by a pathogen associated with an antigenic agent. These "associations" are not necessarily direct correlations. For these reasons, the rejection is maintained. Correction is required.

***Claim Rejections - 35 USC § 102 and 103***

7. In view of the amended claims, the rejection of claims 1-3, 7-13, 15-19 and 22 under 35 U.S.C. 102(b) is withdrawn, as is the rejection of claims 4-6 and 14 under 35 U.S.C. 103(a). However, should the new matter in claims 1-19 and 22 be removed, the rejections may be reinstated.

8. Claims 20 and 21 remain rejected under 35 U.S.C. 102(b) as anticipated by Lee (US Patent 5,367,054) for reasons of record. Applicant's arguments have been carefully considered but fail to persuade the withdrawal of the rejection. Applicant's substantive arguments are primarily directed to the following:

- The purification paths for Lee's IgY product involve processes that would result in the removal of transfer factor. Notably, the ultrafiltration step, the gel filtration step and the

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desalting step referred to in Figure 1 (Lee), would all remove transfer factor from the product containing IgY. The ultrafiltration step uses a filter having a pore size larger than transfer factor, which would exclude transfer factor from the resulting IgY preparation. The gel filtration gel beads would trap the transfer factor molecules in their pores. The desalting step uses a dialysis membrane having a molecular weight cut off larger than transfer factor.

- In response, the Office acknowledges that the purification pathways described in Lee's Figure 1 would most likely remove transfer factor from the purified IgY composition. However, Lee does not limit the purification of IgY to the processes in Figure 1. For example, claim 1 of the Lee patent is drawn to a method for purifying IgY from an immune egg by diluting and homogenizing the yolk, extracting the homogenate and recovering the aqueous phase. The aqueous phase not only contains IgY, but would also contain transfer factor. Although Lee does not say that transfer factor is present in the aqueous phase, one would expect transfer factor to be present given the circumstances of which the egg yolks were processed. Even Applicant notes that transfer factor would initially be present in the aqueous phase. Therefore, Applicant's argument is based on further purification steps which are not required according to claim 1 of the Lee patent.
- Lee does not expressly or inherently describe administering to a treated animal a composition that includes an extract of an egg with a sufficient quantity of transfer factor to initiate a T-cell mediated immune response by the treated animal. Applicant argues

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that even if there were residual transfer factor left in Lee's IgY product, it would not be in a quantity sufficiently to induce a T-cell response.

- In response, as noted above, Lee's product resulting from claim 1 (Lee) would result in a purified IgY product containing transfer factor. Lee indicates that the purified products can be used for pharmaceutical purposes, such as passive immunization or a health food ingredient. While it may be preferable to further process the aqueous phase, Lee indicates that the aqueous phase is a purified product and that purified products can be administered (col. 3, lines 38-40 and col. 4, lines 13-19). Lee discloses that the two major products of the invention are the IgY protein obtained as a retentate from ultrafiltration of the aqueous phase and the pure IgY obtained from further processing. Regardless these two major products, Lee also considers the aqueous phase itself to be a purified product that can be further purified (col. 3, lines 52-57).

Therefore, the claims remain rejected as anticipated by Lee.

### *Conclusion*

9. No claim is allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen  
November 23, 2004



JAMES HOUSEL 11/29/04  
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